REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 25-30, 33, 35-46, 48, and 50-53 are currently under consideration. Claims 25, 27-30, 33, and 36-38 are amended and claims 26, 35, 39, 41-46, 48, and 50-53 are cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

Support for the amended claims can be found throughout the specification, for example in the paragraphs beginning on page 9, line 25, and on page 12, line 23, and in Example 4.

II. REJECTION UNDER 35 U.S.C. § 112, 1ST PARAGRAPH IS OVERCOME

Claims 25-30, 33, 35-39, 41-46, 48, and 50-53 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejection is respectfully traversed.

The Office Action contends that the specification is not enabling for any mouse that overexpresses regucalcin or any transgenic rat showing any other bone pathology. Further, the specification is allegedly not enabling for a method of using said animal in a screening method for preventative and therapeutic agents for any bone disease. The Office Action asserts that it is unpredictable that a transgenic mouse would express regucalcin at adequate levels to show any pathology disclosed in the specification. In addition, the Office Action alleges that the specification fails to provide guidance to study any bone pathology associated with the genus of

bone disease other than bone density, bone strength, thickness of cortical bone of diaphysis and length of surrounding outer membrane of cortex in diaphysis.

Initially, Applicants argue that the specification is enabling in view of the breadth of the claims, which are amended herein. Notably, claim 25 is amended to clarify that the claimed invention is directed to a transgenic rat comprising in its genome a transgene comprising the rat regucalcin cDNA homozygously, wherein the transgenic rat overexpresses regucalcin, and shows a decrease in any one or more of bone density, bone strength, and bone thickness of diaphyseal cortex or length of surrounding of cortex. Further, claim 36 is amended to clarify that the screening method of preventive and therapeutic agents is for decrease in bone density, bone strength, and bone thickness of diaphyseal cortex or length of surrounding of cortex. These claim amendments refine the scope of the transgenic model (rat, homozygous) and the claimed bone pathology exhibited by the transgenic model (decrease in any of bone density, bone strength, and bone thickness of diaphyseal cortex or length of surrounding of cortex) in claim 25, and the bone morphological measurements (decrease in any of bone density, bone strength, and bone thickness of diaphyseal cortex or length of surrounding of cortex) in claim 36. As such, the scope of the instant claims is revised.

Furthermore, the specification provides sufficient guidance for transgenic rat comprising the rat regucalcin cDNA, as exemplified in the paragraph beginning on page 25, line 29, and in Example 2. Additionally, the specification provides ample guidance for transgenic rat showing decrease in bone density, bone strength, and bone thickness of diaphyseal cortex or length of surrounding of cortex, as demonstrated in the paragraph beginning on page 30, line 29, and in Example 4.

Moreover, the Office Action concedes that the specification is "enabling for a transgenic rat comprising in its genome a transgene comprising the rat regucalcin cDNA, wherein the said transgenic rat overexpresses regucalcin, and shows a decrease in bone density, bone strength, and bone thickness" and "a method of using said transgenic at in a screening method for preventative and therapeutics agents" (see Office Action, page 3, 2nd paragraph). Hence, the instant claims are clearly enabled by the specification.

Accordingly, reconsideration and withdrawal of the Section 112 rejections is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

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